NONCONFIDENTIAL

04-1323

In The
United States Court of Appeals
For the Federal Circuit

ARTHROCARE CORPORATION,

Plaintiff-Counterclaim Defendant-Appellee,

and

ETHICON, INC.,

Counterclaim Defendant-Appellee,

v.

SMITH & NEPHEW, INC.,

Defendant-Counterclaim Plaintiff- Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE IN 01-504-SLR, CHIEF JUDGE SUE L. ROBINSON

SMITH & NEPHEW'S REPLY TO ARTHROCARE'S RESPONSE TO SMITH & NEPHEW'S EMERGENCY MOTION TO STAY INJUNCTION PENDING APPEAL

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I. INTRODUCTION

ArthroCare has failed to overcome Smith & Nephew's strong showing that a stay should be granted in this appeal, particularly where the issues of patent validity and enforceability are in serious doubt, and Smith & Nephew has made a strong showing under the *Standard Havens* factors.

II. ANY INJUNCTION SHOULD BE STAYED UNTIL THE ANTITRUST COUNTERCLAIM IS FINALLY ADJUDICATED

A. Smith & Nephew Must Be Allowed to Respond Directly to ArthroCare's Arguments

In its Response ("Resp."), ArthroCare has not said one word in support of the district court's decision to grant ArthroCare's motion to dismiss Smith & Nephew's antitrust counterclaim while briefing had been stayed on the motion. Apparently, ArthroCare concedes that the court's decision was improper.

Instead, ArthroCare argues that due process was nevertheless satisfied by Smith & Nephew's motion for reconsideration, which was only filed ***after*** the district court had granted the motion to dismiss. For support, ArthroCare relies on *Greene v. WCI Holdings Corp.*, 136 F.3d 313, 316 (2d Cir. 1998) (Resp. at 3), but its argument is unavailing. In *Greene,* ***prior to*** dismissing the complaint, the plaintiff was permitted to file "extensive written arguments with the district court, which allowed him to address specific issues of law with which the district court was concerned," and thus the court held it was not error to deny oral argument on the motion. *Id.* at 316. Conversely, Smith & Nephew was prevented from presenting ***any*** arguments -- written or oral -- to the district court to respond to ArthroCare's motion to dismiss the antitrust counterclaim.

Moreover, the motion for reconsideration did not permit Smith & Nephew to respond to ArthroCare's motion to dismiss "in a meaningful way." *See Id.* Since it was only a motion for reconsideration, it was directed primarily to the district court's procedural errors, rather than the merits of ArthroCare's motion to dismiss. In fact, Smith & Nephew filed a separate motion to lift the stay and permit it to file a substantive response to the motion to dismiss, but the district court denied that motion, even though it was unopposed by ArthroCare. (Mot. Ex. 9; Reply Ex. 36).

Therefore, ArthroCare has not overcome the fact that Smith & Nephew was denied due process, and the district court improperly granted the motion to dismiss.

B. Smith & Nephew's Antitrust Counterclaim Meets the Pleading Requirements of Federal Rule of Civil Procedure 8

Smith & Nephew's counterclaim plainly states a claim for which relief may be granted -- it sets out the necessary elements of an antitrust claim under ¶ 1 of the Sherman Act in "simple, concise, and direct" terms. Fed. R. Civ. P. 8(e)(1).

In the third circuit, where the underlying case arose, "[t]hree elements must be alleged to sustain a cause of action under section 1 of the Sherman Act...a contract, combination or conspiracy; a restraint of trade; and an effect on interstate commerce." *Fuentes v. South Hills Cardiology*, 946 F.2d 196, 198 (3d Cir. 1991). Smith & Nephew has sufficiently set out these elements. Rule 8 does not require more. *Id.* at 202 ("allegations identifying the conspiracy's participants, purpose and motive are sufficient to survive a motion to dismiss"). This is particularly important in antitrust cases because the evidence necessary to prove the antitrust claim is in the hands of the conspirators. *Hospital Building Co. v. Trustees of Rex*

Hospital, 425 U.S. 738, 746 (1976). Thus, "dismissal prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Id.*[1]

ArthroCare also asserts that the "counterclaim never says [redacted] (Resp. at 8). ArthroCare is incorrect. Indeed paragraphs 33-35 and 37, which, along with all reasonable inferences drawn therefrom must be accepted as true, say just that. (*See* Mot. at 8). Rule 8 does not require more than giving "fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Swierkiewicz v. Soreman N.A.*, 534 U.S. 506, 512 (2002) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).[2]

ArthroCare further argues that Smith & Nephew cannot plead antitrust injury because the jury found that its patents were valid and infringed. (Resp. at 9-10). ArthroCare principally relies on *Axis, S.p.A v. Micafil, Inc.*, 870 F.2d 1105 (6th Cir.), *cert denied*, 493 U.S. 823 (1989). But in that case, the court held that the plaintiff had suffered no antitrust injury because patents held by third parties had foreclosed plaintiff from entering the market prior to and independently of the defendant's unlawful conduct (*i.e.*, acquisition of a patent-holding firm). *See Id.* at 1111. The court was also careful to point out that the plaintiff in that case failed to allege that the antitrust defendant "violated the antitrust laws by misusing its patents or licences." *Id.* Similarly, the court emphasized that the antitrust

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[1] Discovery regarding the antitrust counterclaim was also stayed (Mot. Ex. 11 at 6), so Smith & Nephew has never been able to flesh out its antitrust defense.

[2] Rule 8 also recognizes that alternative theories may be pled. Thus, the fact that the counterclaim also included additional allegations that the lawsuit was baseless, does "not ma[k]e insufficient" Smith & Nephew's allegations of an antitrust claim based on the collusion between ArthroCare and Ethicon. Fed. R. Civ. P. 8(e)(2).

defendant in that case, unlike the ArthroCare/Ethicon combination here, "never dominated the U.S. market" for the relevant product. *Id.* Finally, that case, unlike Smith & Nephew's counterclaim here, involved solely unilateral conduct, not a conspiracy between two dominant firms to exclude competition. *Id.*[3]

ArthroCare does not dispute that Smith & Nephew's antitrust counterclaim, if successful, would render all of the patents-in-suit unenforceable. Thus, since the district court's dismissal of that counterclaim was improper, any injunction should be stayed pending appeal and final adjudication of the counterclaim.

III. SMITH & NEPHEW HAS A HIGH PROBABILITY OF SUCCEEDING ON APPEAL

A. ArthroCare Grossly Overstates the Challenges Smith & Nephew Faces on Appeal

ArthroCare argues that "it is entitled to an injunction if just one of the 16 claims is upheld on appeal." (Resp. at 1, 11-12). In so arguing, ArthroCare suggests that Smith & Nephew cannot avoid an injunction unless it prevails on every one of 16 separate issues. However, ArthroCare's argument ignores the legal reality that if Smith & Nephew prevails on just ***one*** of its issues on appeal, any injunction would be rendered invalid because its scope would change.

For example, in its Motion, Smith & Nephew showed that if it prevailed on the construction of the claim term "connector," the '536 patent would not be infringed. Since that is the only apparatus patent, any injunction against making the accused products in the United States would be void. (Mot. at 15, n.10).

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[3] ArthroCare's other cases, *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477 (1977) and *City of Pittsburg v. West Penn. Power Co.*, 147 F.3d 256 (3d Cir. 1998), do not even involve patents or the issue of patent misuse.

ArthroCare admits that this result would occur, recognizing that if Smith & Nephew wins on the construction of "connector," all that would remain would be the '882 and '592 method patents. (Resp. at 13).

Smith & Nephew also intends to raise other issues on appeal, which by themselves would dispose of the ***entirety*** of the jury's verdict. For example, Smith & Nephew sought a new trial on the ground that the district court's admission of so-called "copying" evidence was improper, inflammatory, and unduly prejudicial. (Reply Ex. 37 at 17-27). If Smith & Nephew prevails on just this one issue, the entire case will be remanded for a new trial on all issues. *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 514 (Fed. Cir. 1990):

> Gencor, in addition, may prevail in the appeal without showing that the judgment must be reversed if it shows that the district court abused its discretion in denying its motion for a new trial. An order vacating the judgment would be success on the merits of the appeal.

Thus, the scope of any injunction would be significantly impacted if Smith & Nephew prevailed on just one of its issues on appeal.

B. The Balance of *Standard Havens* Factors Favors a Stay

The four factors this Court set forth in *Standard Havens*, 897 F.2d at 512 (*See* Mot. at 11), need not be given equal weight. For example, in *Standard Havens*, this Court held that the stronger the showing of likelihood of success on the merits, the less heavily the balance of harms need tip in movant's favor. Conversely, if the harm factors weigh heavily in movant's favor, it need only demonstrate a substantial case on the merits. *Id.*, 897 F.2d at 513. Here, there is not only a strong likelihood of success on the merits, but the balance of harms,

including harm to the public (*i.e.*, surgeons and patients), tips heavily in favor of maintaining the *status quo* and granting a stay of the injunction pending appeal.

1. Substantial Invalidity Questions Exist

Particularly in light of the pending reexaminations, Smith & Nephew has demonstrated that there is high likelihood that the patents will be found invalid.

ArthroCare disputes this by arguing that the prior art has already been considered by the PTO. (Resp. at 12).[4] However, that argument was of no consequence in *Standard Havens* (897 F.2d at 514), and for the same reasons is of no consequence here. For example, as the reexamination examiner has made clear, "Roos '198 discloses an electrically conducting fluid in claim 1. The teaching of an electrically conducting fluid in Roos '198 was ***not*** considered in the prosecution of the application, which became the Eggers et al. patent." (Mot. Ex. 23 at 2) (emphasis added). It is highly likely that this Court will come to the same conclusion once it hears Smith & Nephew's full arguments during appeal.[5]

[4] The fact that the '536 patent has previously been reexamined does not change the likelihood of success on appeal. First, the prior reexamination was conducted by the same examiner that examined the original application. (*Compare* Mot. Ex. 13 with Reply Ex. 38). An original examiner is less likely to change his decision on reexamination, a fact that the PTO inherently recognizes. *See* M.P.E.P. 2236. Moreover, the current reexamination examiner has determined that the prior art "has been presented in a new light with a material new argument or interpretation," that was not considered in the prior reexamination. (Mot. Ex. 21 at 2-3).

[5] During both prior prosecution and the trial, ArthroCare argued that the Roos '198 prior art did not disclose an electrically conducting fluid, and the jury apparently accepted that argument. However, the reexamination examiner's contrary conclusion is well supported by the reference itself. *See* Roos claim 1, which explicitly teaches the use of "liquid to provide electrical conductance," *i.e.*, electrically conducting fluid. (Reply Ex. 39, col. 7, lines 60-61).

2. Substantial Claim Construction Issues Exist

ArthroCare mischaracterizes Smith & Nephew's argument regarding reading the "connector" limitation out of the claim.[6] It has never been argued that "located at the proximal end of the shaft" is read out of the claim by the district court's construction. (*See* Mot. at 14). Rather, "connector" itself is read out of the claim, because if one were to substitute that term for the court's claim construction (underlined), the entire limitation would read "a structure that electrically links the electrode terminal to the high frequency power supply near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply." This makes no sense and gives no meaningful definition of "connector."

Thus, there is a strong likelihood that this Court will reverse the district court's claim construction.[7]

3. ArthroCare will Not be Harmed by a Stay of Injunction

ArthroCare has demonstrated no real harm that it will incur if the injunction is stayed pending appeal.[8] As shown in Smith & Nephew's Motion, the

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[6] While Smith & Nephew described only one claim construction error in its Motion, it intends to raise several others on appeal, each of which would be completely dispositive of the patent in which it is found. (*See* Mot. at 15, n.10).

[7] ArthroCare is incorrect when it asserts that Smith & Nephew did not preserve the Certificate of Correction issue for appeal. (Resp. at 15). There is no requirement to make a further objection if such further objection would be futile. *See, e.g., Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1369-70 (Fed. Cir. 2002).

[8] The *Odetics, Inc. v. Storage Techs. Corp.*, 14 F.Supp.2d 785 (D. Minn. 1998) case, on which ArthroCare relies (Resp. at 15-16), holds only that licenses to the patent-in-suit do not lessen the presumption of harm when deciding whether to enjoin an infringer at all. *Id.* at 795. However, the *Odetics* court further held, contrary to ArthroCare's argument, that licensing competitors "less[ens the] likelihood that a stay would cause any substantial harm." *Id.* at 799.

presumption of harm from even a clear showing of patent validity and infringement -- which is not present here -- is rebuttable. (Mot. at 16).

ArthroCare tries to distinguish the cases relied on by Smith & Nephew by asserting that it has "never willingly licensed anyone." (Resp. at 16, n.6). But this alleged distinction is absurd. No one forced ArthroCare to license the rest of the industry. Certainly, no-one forced ArthroCare to settle a lawsuit in which the district court had found its patents likely invalid, by granting Ethicon [redacted]. Thus, ArthroCare's attempt to distinguish Smith & Nephew's cases is unavailing.

ArthroCare argues, without even trying to offer evidentiary support, that it has somehow lost goodwill or opportunities for research and development. (Resp. at 16). In fact, its most recent financial results prove just the opposite -- that its product revenues have actually ***increased 30%*** from 2003 to 2004. (Reply Ex. 40). This is hardly evidence of a loss of goodwill. Similarly, ArthroCare's research and development is actually increasing, rather than decreasing as it argues:

> The increase in research and development expenses in 2003 as compared to 2002 is primarily due to our continued investment in Coblation technology... The increase consists of $1.2 million in increased compensation and related expenses due to increasing headcount, and $0.6 million in increased prototype development costs.

(Reply Ex. 41 at 36). An increase in spending and headcount is hardly evidence of a company's research and development being irreparably harmed.

Thus, Smith & Nephew's presence in the market has not irreparably harmed ArthroCare, and a stay of injunction will not result in any harm.

4. The Public Interest Strongly Favors a Stay

ArthroCare has also failed to overcome Smith & Nephew's showing that surgeons and their patients will be greatly harmed by an immediate injunction.

Most noticeably, ArthroCare has not shown that any other product on the market performs like the Smith & Nephew ElectroBlade. It argues that surgeons who evaluated the ElectroBlade would have used an ArthroCare probe for the same procedure. (Resp. at 18). However, the document cited by ArthroCare shows just the opposite; it shows that the doctor would have used a full radius blade (*i.e.*, a mechanical shaver) ***and*** an ArthroCare probe together. (Resp. Ex. 12 at SN46966). As Smith & Nephew pointed out in its Motion, without the ElectroBlade, surgeons generally switch between a mechanical shaver and RF coagulation device, increasing surgical time as well as patient morbity and the use of tourniquets. (Mot. at 19; *see also Id.* at SN46967 (noting that fewer instruments were used compared to procedures without the ElectroBlade)).

In fact, ArthroCare's own documents undercut its argument that its products can substitute for the mechanical shaver capability of the ElectroBlade: [redacted] ArthroCare also argues that the Linvatec Trident is similar to the ElectroBlade. (Resp. at 18, n. 8). This is also incorrect. The Trident is a mechanical shaver with an RF device on the opposite side of the shaver blade, and therefore "cannot mechanically resect and coagulate simultaneously." (Mot. Ex. 31).

Thus, there would be substantial harm to the public in removing these uniquely beneficial medical devices from the market. The injunction should be stayed pending appeal to avoid such harm.

5. Balance of the Harms

Because Smith & Nephew has a high likelihood of success on appeal, the balance of the harms need only tip slightly in its favor. *Standard Havens*, 897 F.2d at 513. In fact, the balance of harms tips heavily in favor of a stay as well.

As shown above, ArthroCare has failed to show it will suffer any real irreparable harm should this Court maintain the *status quo* and grant a stay. If an injunction was stayed and ArthroCare was to prevail on every issue on appeal it would have monetary damages available for infringement, which it has shown is sufficient by licensing every other competitor in the market. However, with an injunction in place, if Smith & Nephew were to prevail on any issue on appeal it would have ***no*** remedy for the harm it would suffer while off the market. Smith & Nephew will have been wrongly removed from a market whose barrier to entry is high and its proper reentry would be highly improbable.

Thus, the balance of harms further supports a stay of the injunction.

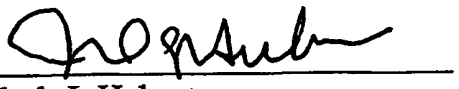
IV. SMITH & NEPHEW IS WILLING TO POST A BOND

While Smith & Nephew contends that no bond should be necessary, it would be willing to consider a reasonable bond required by this Court to support the stay.

V. CONCLUSION

For the foregoing reasons, and the reasons set forth in its Motion, Smith & Nephew respectfully requests that this Court stay any injunction pending appeal.

Respectfully Submitted,



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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of May, 2004, I caused a copy of the foregoing **NON-CONFIDENTIAL VERSION OF SMITH & NEPHEW'S REPLY TO ARTHROCARE'S RESPONSE TO SMITH & NEPHEW'S EMERGENCY MOTION TO STAY INJUNCTION PENDING APPEAL** to be served as follows:

Via Federal Express Jack J. Blumenfeld Morris, Nichols, Arsht & Tunnell 1201 North Market Street P.O. Box 1347 Wilmington, DE 19899-1347	Attorneys for Plaintiff-Counterclaim Defendant-Appellee Arthrocare Corporation
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Judith Best

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION, Plaintiff, v. SMITH & NEPHEW, INC. Defendant.	C.A. No. 01-504-SLR
SMITH & NEPHEW, INC., Counterclaim Plaintiff, v. ARTHROCARE CORPORATION, AND ETHICON, INC., Counterclaim Defendants.	

SMITH & NEPHEW'S UNOPPOSED MOTION TO LIFT STAY TO PERMIT SMITH & NEPHEW TO FILE AN ANSWERING BRIEF IN OPPOSITION TO ARHTROCARE'S MOTION TO DISMISS SMITH & NEPHEW'S ANTITRUST COUNTERCLAIM

Defendant, Smith & Nephew, Inc. ("Smith & Nephew") hereby moves to lift the stay previously imposed by the Court and permit Smith & Nephew to file an Answering Brief in opposition to the motion filed by ArthroCare Corp. ("ArthroCare") to dismiss Smith & Nephew's antitrust counterclaim. ArthroCare states that it does not oppose this motion. In support of this motion, Smith & Nephew states as follows:

1. On May 27, 2003, ArthroCare filed a Motion to Dismiss Smith & Nephew's Antitrust Counterclaim. (D.I. 429, "Motion to Dismiss"). Thereafter, on June 9, 2003, before Smith & Nephew's answering brief was due, the Court held a telephone conference to set a briefing schedule for all post-trial motions in this case. (D.I. 447).

2. During that June 9, 2003 teleconference, with respect to all matters relating to the issues of antitrust, damages and willfulness, the Court stayed all further proceedings, including briefing with respect to the Motion to Dismiss. (*Id.* at 10:15-22, 14:21-23, 15:2-5, 15:21-16:1). The Court also advised the parties that no formal order would issue because the orders staying the various issues discussed during the teleconference would be reflected in the transcript. (*Id.* at 12:21-24).

3. No further order has ever issued which lifted or otherwise addressed the Court's stay of any further briefing with respect to ArthroCare's Motion to Dismiss.

4. On March 10, 2004 the Court issued Orders (D.I. 482 and 484) in which the Court granted ArthroCare's Motion to Dismiss, as well as its motion for a permanent injunction. ("Motion for Permanent Injunction") (D.I. 424).[1]

5. In the memorandum opinion supporting the Court's Order granting the Motion to Dismiss, the Court inferred from the absence of an answering brief filed by Smith & Nephew that the motion was not opposed: "Smith & Nephew has not responded... [t]he court, therefore, presumes that Smith & Nephew does not oppose the

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[1] Defendant Smith & Nephew has filed a motion pursuant to Local Rule 7.1.5 for reconsideration (D.I. 488) because the Order granting the Motion to Dismiss was based on two mistaken assumptions: 1) that the motion was unopposed; and 2) that the viability of Smith & Nephew's antitrust counterclaim depends on a showing that this action was objectively baseless "sham" litigation. Because the erroneous dismissal of Smith & Nephew's antitrust counterclaims was the predicate for the court's finding that "it is not premature to enter an injunction" (D.I. 483 at 90, n.29), Smith & Nephew also requested reconsideration of the court's Order granting the Motion for Permanent Injunction. The injustice of the ruling on the antitrust counterclaim was compounded when ArthroCare ignored the Court's stay of briefing in opposing the motion for reconsideration and instead repeated its arguments in support of its motion to dismiss, knowing that Smith & Nephew again would have no opportunity to respond. Local Rule 7.1.5 ("The Court will determine from the motion and answer whether reargument will be granted."); *Stairmaster Sports/Medical Products, Inc. v. Groupe Procycle, Inc.*, 25 F.Supp.2d 270, 292 (D. Del. 1998)(Local Rule 7.1.5 "permits filing of only one brief per side with an emphasis on brevity ... StairMaster, apparently anxious to get the last word, filed a reply brief while Local Rule 7.1.5 distinctly sets out that 'the Court will determine from the motion and answer whether argument will be granted.'").

motion." (D.I. 483, at n. 1). This presumption was in error. Smith & Nephew made its opposition to the Motion to Dismiss known when it opposed the Motion for Permanent Injunction, as the Court acknowledged. (*Id.*). It was given no further opportunity to oppose because the Court stayed briefing on the Motion to Dismiss and all other activity related to the antitrust counterclaim.

6. Moreover, because the Court did not have a brief in opposition to the Motion to Dismiss, it adopted ArthroCare's misleading, incomplete and erroneous characterization of the counterclaim as a simple "sham" litigation claim and found it barred by the jury's verdict and the *Noerr-Pennington* doctrine. In particular, the Court characterized Smith & Nephew's antitrust counterclaim as "premised on the idea that ArthroCare and Ethicon[2] filed 'sham' litigation against Smith & Nephew to prevent or restrain it from entering the arthroscopic surgery market." Undoubtedly, this incomplete and inaccurate characterization of the antitrust counterclaim was derived in large part from the unanswered arguments made in ArthroCare's brief in support of its Motion to Dismiss. (D.I. 430). For example, ArthroCare argued there that, "Smith & Nephew had to make these allegations [that the lawsuit was objectively baseless] because ArthroCare's patent infringement suit ***cannot give rise to antitrust liability unless*** Smith & Nephew pleads and proves that ArthroCare has engaged in 'sham litigation.'" (D.I. 430 at 6). (emphasis added). However, Smith & Nephew's antitrust counterclaim is not so limited.

7. Fundamental fairness, as well as due process, requires that Smith & Nephew be given an opportunity to be heard on the merits in connection with the Motion to Dismiss. *Dougherty v. Harper's Magazine Co.*, 537 F.2d 758 (3d Cir. 1976). In *Dougherty*, the court stated:

> Rule 12(d), FRCP requires that a Rule 12(b)(6) motion for dismissal ... may be disposed of only after a hearing, which affords an opportunity to present legal arguments either orally, in writing, or both at the District Court's discretion. The right to hearing is "the essence of our judicial

[2] Ethicon, Inc. is not a plaintiff in this case. Ethicon was added as a counterclaim defendant on the antitrust counterclaim included in the Amended Answer and Counterclaims of Smith & Nephew, Inc. (D.I. 219).

> system, and the judge's feeling that the case is probably frivolous does not justify bypassing that right." ... In *Jordan v. County of Montgomery, Pennsylvania*, ... we held that an order dismissing a complaint under Rule 12(b)(6), entered without affording the plaintiff an opportunity to be heard, must be reversed. We note that in *Council of Federated Organizations v. Mize*, 339 F.2d 898 (5th Cir. 1964), the Court characterized as a denial of due process the entry of an order dismissing the complaint for failure to state a claim without giving the plaintiff an opportunity to be heard.

Id. at 761 (internal citations omitted). Similarly, the Supreme Court has held:

> Under Rule 12(b)(6), a plaintiff with an arguable claim is ordinarily accorded notice of a pending motion to dismiss for failure to state a claim and an opportunity to amend the complaint before the motion is ruled upon. These procedures alert him to the legal theory underlying the defendant's challenge, and enable him meaningfully to respond by opposing the motion to dismiss on legal grounds or by clarifying his factual allegations so as to conform with the requirements of a valid legal cause of action. This adversarial process also crystallizes the pertinent issues and facilitates appellate review of a trial court dismissal by creating a more complete record of the case.

Neitzke v. Williams, 490 U.S. 319, 329-30 (1989).

Conclusion

8. For the reasons set forth herein, Smith & Nephew respectfully requests that the Court lift its June 9, 2003 stay with respect to briefing on ArthroCare's Motion to Dismiss, and allow Smith & Nephew to file an Opposition to the Motion.

Dated: April 6, 2004

FISH & RICHARDSON P.C.

By: _____

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RULE 7.1.1 CERTIFICATE

I hereby certify that I have contacted counsel for ArthroCare on the matters set forth in the Motion. I further certify that I ArthroCare's counsel does not oppose our motion to lift the stay to permit Smith & Nephew to file an answering brief.

Eugene B. Joswick

Exhibit 37
Confidential Exhibit Removed

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

CONTROL NUMBER	FILING DATE	PATENT UNDER REEXAMINATION	ATTORNEY DOCKET NO.
90/005,601	12/30/99	5697536	

QM31/0202

JAMES M HESLIN
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SAN FRANCISCO CA 94105-1492

EXAMINER	
MENDEZ, M	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: Email ~~02/03/00~~ 10-27-00

ORDER GRANTING/DENYING REQUEST FOR REEXAMINATION

The request for reexamination has been considered. Identification of the claims, the references relied on, and the rationale supporting the determination are attached.

Attachment(s): ☐ PTO-892, ☒ PTO-1449, ☐ Other: _____.

1. ☒ The request for reexamination is GRANTED.

RESPONSE TIMES ARE SET TO EXPIRE AS FOLLOWS:

For Patent Owner's Statement (optional): TWO MONTHS from the mailing date hereof. 37 CFR 1.530(b). EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).

For Requester's reply (optional): TWO MONTHS from the date of service of any patent owner's statement. 37 CFR 1.535. NO EXTENSION OF TIME IS PERMITTED. If patent owner does not file a timely statement under 37 C.F.R. 1.530(b), no reply by requester is permitted.

2. ☐ The request for reexamination is DENIED.

This decision is not appealable. 35 U.S.C. 303(c). Requester may seek review by petition to the Commissioner within ONE MONTH from the mailing date hereof. 37 CFR 1.515(c). EXTENSIONS OF TIME ONLY UNDER 37 CFR 1.183.

In due course, a refund under 37 CFR 1.26(c) will be made to requester (listed below if not patent owner) ☐ by Treasury check, ☐ by credit to Deposit Account No. _____ unless notified otherwise. 35 U.S.C. 303(c).

(Third party requester's correspondence address)

Reexam Control No.: 90/005,601
Art Unit 3763

A substantial new question of patentability affecting at least claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 and 63 of U.S. Patent No. 5,697,536 to Eggers et al. is raised by the request.

The request indicates that the requester considers at least claims 1-3, 14, 16, 22, 27, 30, 33, 38, 41-48, 55, 57, 60 and 63 of Eggers et al. as being anticipated by U.S. Patent No. 4,116,198 to Roos under 35 U.S.C. 102.

It is agreed that a reasonable examiner would consider U.S. Patent No. 4,116,198 to Roos to be important prior art which would clearly be material in the examination of the claims as pointed out in detail in the request.

The reference is therefore considered to raise a substantial question of patentability.

Accordingly, reexamination of all the patent claims is deemed proper.

Manuel Antonio Mendez
January 25, 2000

KEVIN WOOD COGGINS
SUPERVISORY PATENT EXAMINER

90/005,[illegible]1

Page [illegible] of [illegible]

FORM PTO-1449	Atty. Docket No.: [illegible]	Patent No.: [illegible]5,697,536
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Inventor(s): [illegible]Eggers et al.	
	Issue Date [illegible]12/16/97	Group Art: [illegible]unknown

DEC 10 1997 PATENT AND TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Sub Class	Filing Date If Appropriate
	AA	4,116,198	09/26/78	Roos	128	303.15	05/14/76
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		Document No.	Date	Country	Class	Sub Class	Translation Yes	No
	AL							
	AM							
	AN							

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AO	
	AP	
	AQ	

EXAMINER: [signature] DATE CONSIDERED: January 20, 00

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

53

United States Patent [19]

Roos

[11] **4,116,198**

[45] **Sep. 26, 1978**

[54] **ELECTRO - SURGICAL DEVICE**

[75] Inventor: **Eberhard Roos, Tuttlingen, Fed. Rep. of Germany**

[73] Assignee: **DELMA, elektro und medizinische Apparatebaugesellschaft m.b.H., Tuttlingen, Fed. Rep. of Germany**

[21] Appl. No.: **686,600**

[22] Filed: **May 14, 1976**

[30] **Foreign Application Priority Data**

May 15, 1975 [DE] Fed. Rep. of Germany 2521719

[51] Int. Cl.[2] A61B 17/32

[52] U.S. Cl. 128/303.15

[58] Field of Search 128/303.13–303.18

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Primary Examiner—Lee S. Cohen

[57] **ABSTRACT**

Electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue, wherein the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope.

20 Claims, 9 Drawing Figures

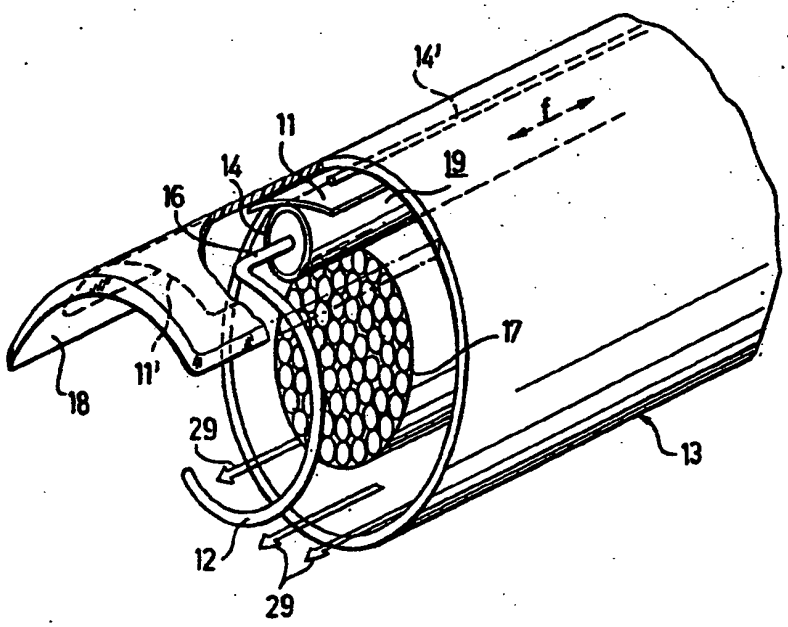


Fig.1

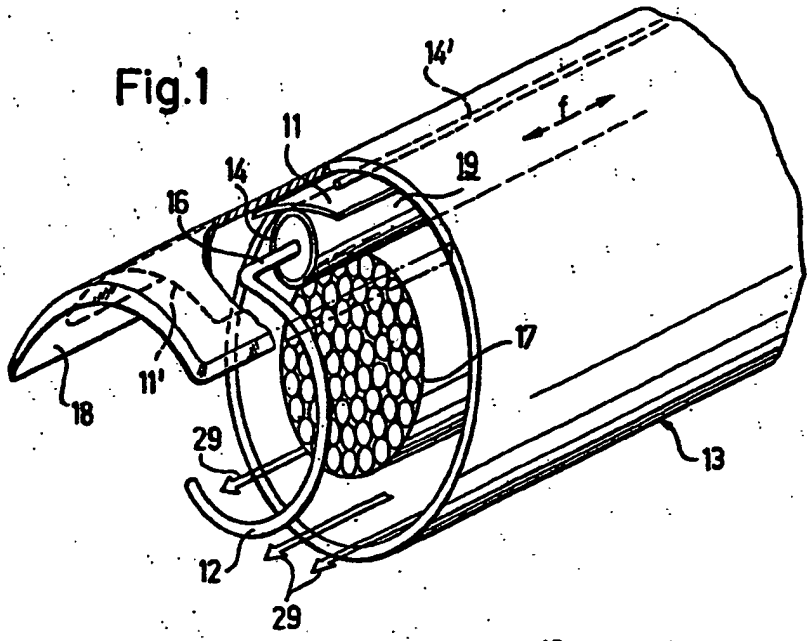

14'
f
11
14
19
16
17
11'
18
29
13
12
29

Fig.2

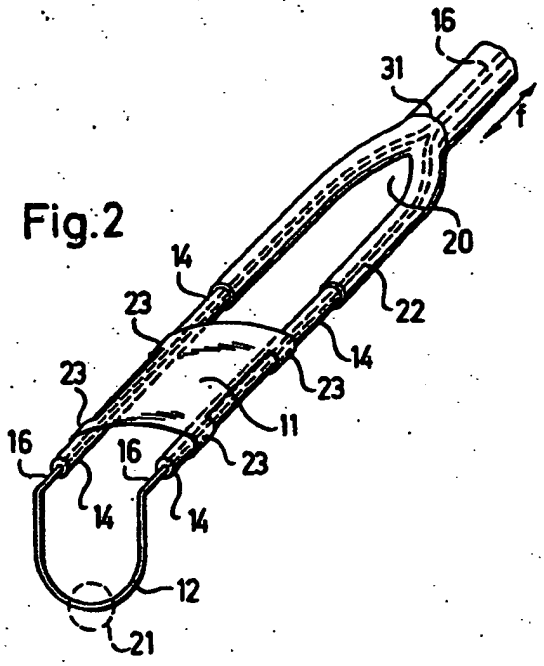

16
31
f
20
14
22
23
14
23
23
11
16
23
16
14
14
12
21

Fig.3

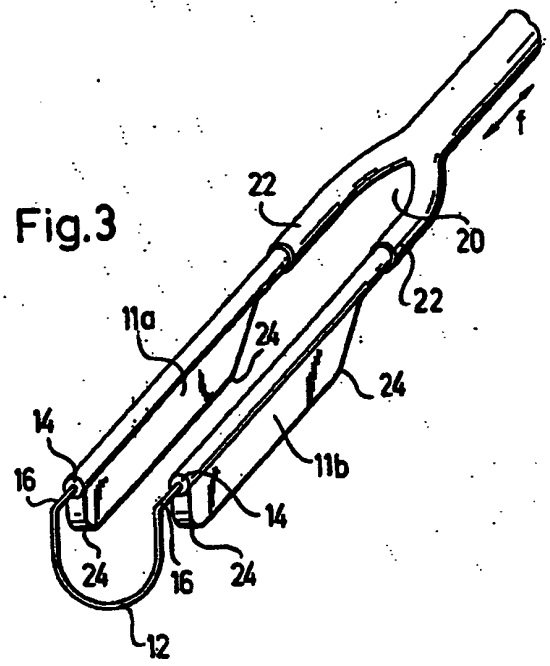

f
22
20
22
11a
24
24
14
16
11b
14
24
16
24
12

Fig.4

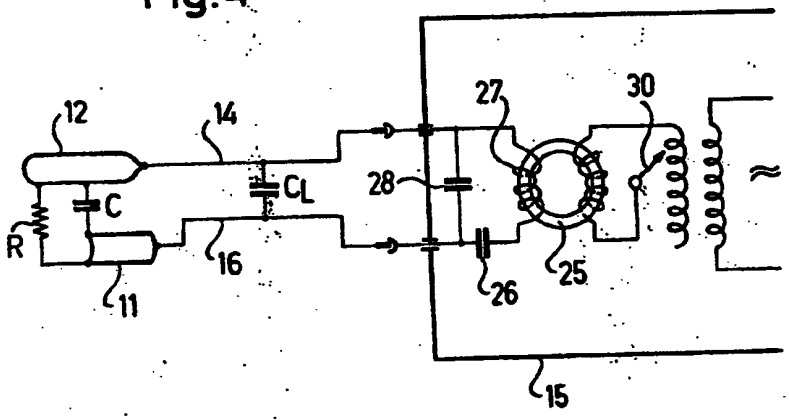

12
14
27
30
C
CL
28
R
16
26
25
11
15

Fig.5

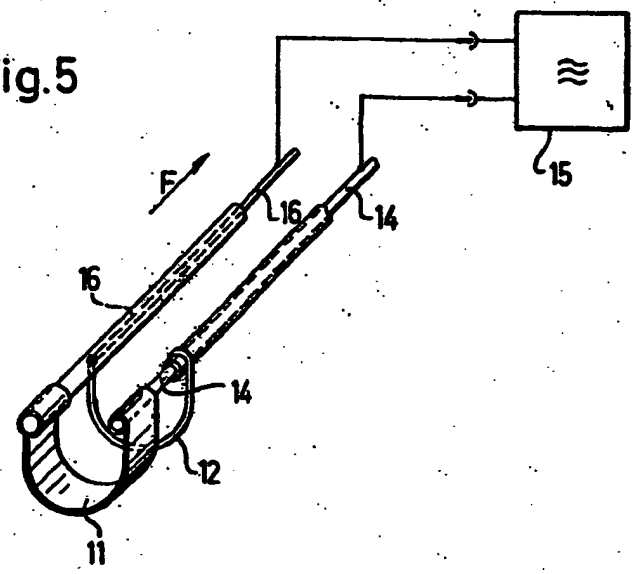


Fig.6

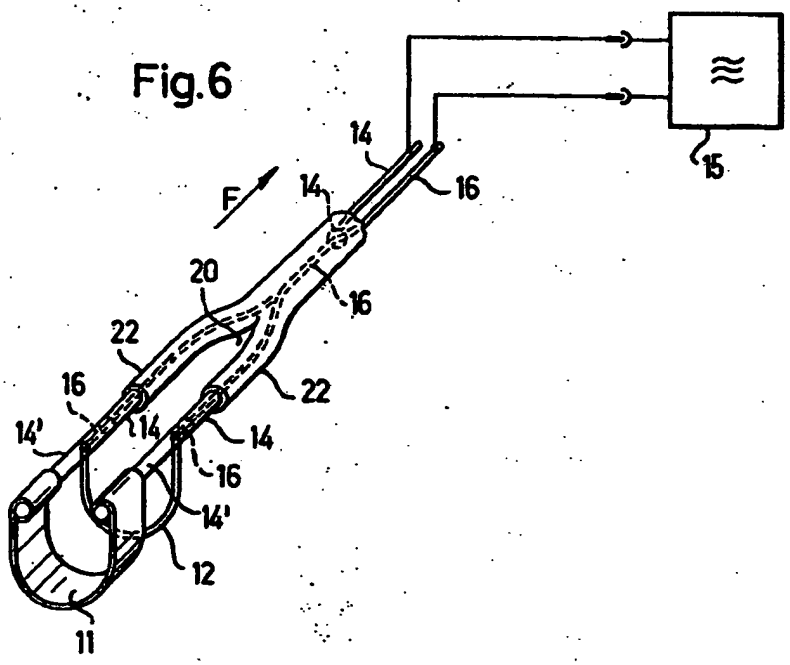


Fig.7

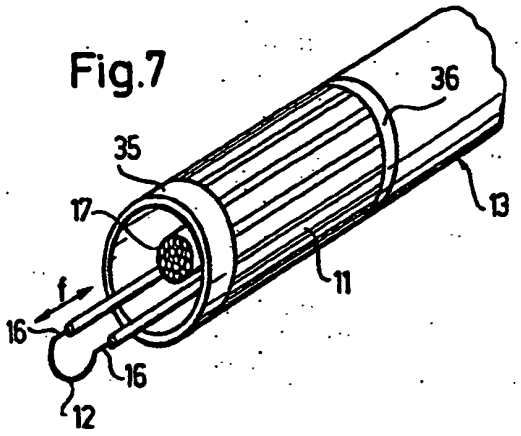


Fig.8

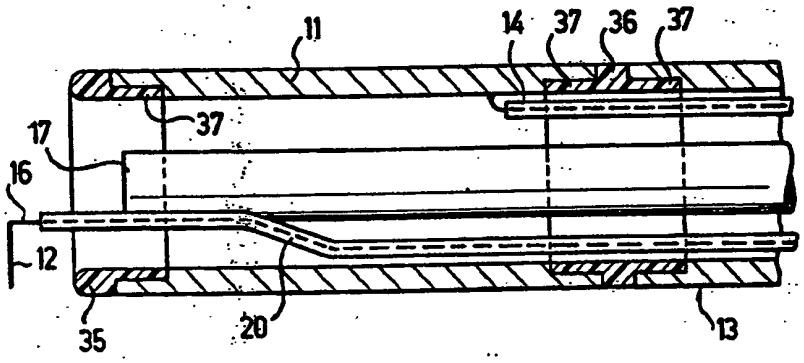
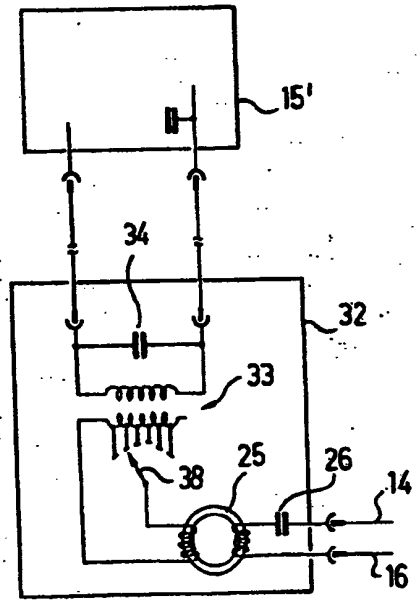


Fig.9



ELECTRO - SURGICAL DEVICE

BACKGROUND OF THE INVENTION

The invention relates to an electro-surgical device with an insulated cable which can be passed through an endoscope, to which can be connected the pole of a high frequency generator, said pole being insulated from earth potential and on whose end facing the body cavity is provided a small-area treatment electrode projecting from the endoscope, said treatment electrode cooperating with a large-area neutral electrode connected to the other pole of the high frequency generator which is insulated from earth potential in such a way that due to the high current density in the area of the treatment electrode, a generation of heat takes place which is adequate for separating or coagulating tissue.

Electro-surgical devices of this type permit electro-surgical operations of the filled bladder (electro-resection, e.g. of bladder tumors and the prostate glands) using endoscopes, particularly resectoscopes and cystoscopes.

The high degree of development in the endoscope field has resulted in operations in the bladder and on the prostate glands using these instruments and by means of electro-surgery have become the most commonly used operating procedure.

In known devices of this type, high frequency alternating current is fed via an earthed neutral electrode on the one hand and via a sparking ball or cutting loop well insulated relative to the outer shaft of the endoscope on the other to the operating area for coagulation purposes in the case of hemorrhages. Due to the relatively small area of the cutting loop compared to the area of the neutral electrode applied externally to the patient's body a very high current density occurs in the area of the cutting loop which results in heat generation in the tissue linked with the bursting of the tissue cells through steam generation and consequently a separation of the tissues. For the desired cutting or coagulating effects, the necessary power values of the high frequency current applied vary between 120 and 150 W.

As the leads from the high frequency generator to the cutting electrode have to be passed through the metallic endoscope, the distances between the high frequency-carrying lead and the remaining metal parts of the endoscope insulated therefrom are so small that capacitances of considerable size exist between these metal parts. Thus, to a certain extent, the endoscope forms a capacitor via which part of the applied capacity flows away as leakage current onto the tissue engaging with the metal endoscope shaft. A further, still larger portion of the applied capacity flows from the cutting loop via the washing water directly to the metal parts of the endoscope shaft located in the washing water flow and from there to the engaging tissue. Thus, uncontrollable electrical conditions in the urethral tissue engaging with the endoscope and the unequal distribution of lubricants with insulating properties on the endoscope shaft can cause critical current densities when the leakage current passes to the urethra and this results in burns.

These difficulties would not be eliminated by coating the endoscope shaft with tubes of high-grade insulating material, because the slightest damage to the shaft insulation due to the very high current densities occur during the passage of the leakage current would, in fact, increase the danger of burning due to the damage. However, if the endoscope shaft insulation remains intact, the entire leakage current is led off to the points where the operator is in contact with the endoscope leading to burns to the operator's face or to the eye in contact with the metal escutcheons of the transparent optics.

Neutral electrode isolation from earth potential cannot prevent the passage of the leakage currents to the operator. As the neutral electrode acts as an opposite pole to the cutting or coagulation electrode between the patient and the earthed operating table, it is capacitively connected to earth potential. Therefore, the cutting loop and the leakage current flown therefrom together with its voltage are earthed. Since, in any case, the operator largely carries the earth potential, the passage of the leakage current to the operator cannot be avoided by the measures in question.

BRIEF SUMMARY OF THE INVENTION

The problem of the invention is therefore to provide an electro-surgical device of the type indicated hereinbefore where undesired burns to the urethra and the operator are effectively avoided.

According to the invention, this problem is solved in that the large-area neutral electrode is arranged in the vicinity of the treatment electrode and is connected with the other pole of the high frequency generator by means of an insulated cable which can also be passed through the endoscope. In this way, potential compensation takes place in a spatially very narrowly defined zone. Both the treatment electrode, preferably constructed as a cutting loop and the neutral electrode carry no potential to earth. Leakage current does not flow to the endoscope shaft either from the high frequency lead to the treatment electrode or from the lead to the neutral electrode. Due to the existing capacitance, leakage currents only flow between the leads, but these do not have any external effects.

However, due to the small-area construction of the treatment electrode, a high current density is obtained there, which is adequate for tissue separation or coagulation, whereas the neutral electrode arranged in the immediate vicinity has such a large area that undesired heating is avoided there.

According to a preferred embodiment, the two feed leads comprise a coaxial cable, whose shield forms one conductor and is insulated relative to the endoscope. Thus, the two high frequency leads for the treatment and neutral electrode form a structural unit, which whilst taking up only a small amount of space, can be simply passed through the endoscope together with the optical and washing portions.

In general, the treatment electrode should be in loop form so that the operator's field of vision is uninterrupted.

According to a further embodiment, the centre conductor of the coaxial cable at the front projects above the shield and at this point passes into the treatment electrode. It is thereby particularly advantageous if the shield is constructed as a rigid sleeve and in such a way that the treatment electrode can be moved backwards and forwards relative to the endoscope via the coaxial cable. Thus, in this embodiment, the coaxial cable at the same time forms the support and operating member for the treatment electrode.

The relatively large neutral electrode is advantageously directly fixed to the coaxial cable shield. In this way the neutral electrode can be mounted reliably and immovably in an inexpensive and uncomplicated manner.

Advantageously, the neutral electrode is constructed as an elongated metal sheet slightly curved about the endoscope shaft and extending on either side over the coaxial cable.

According to a further advantageous embodiment, the endoscope has a plastic extension extending over a small portion only of its periphery, whereby the treatment electrode can be moved backwards and forwards beneath the said extension. This plastic extension has the advantage that the washing liquid can be satisfactorily guided and tissue which is not to be treated can be kept away from the treatment electrode. According to the invention, this extension can be used so that the large-area neutral electrode is fixed in insulated manner relative to the endoscope on the inside of the extension. The neutral electrode in then preferably connected with the high frequency generator by an insulated cable secured in the endoscope. In this case, only the other conductor with its insulation and treatment electrode is axially movable.

According to a particularly preferred embodiment, the coaxial cable has a bifurcation just before the body-side end of the endoscope and the two inner conductors eminating from the bifurcation are interconnected by a loop forming the treatment electrode. This construction is particularly stable due to the symmetry conditions resulting from the bifurcation, whereby at the same time the operator still has good visibility through the cutting loop forming the treatment electrode.

If the treatment electrode is used for coagulation purposes, a coagulation sparking ball is fitted to the treatment electrode.

The coaxial cable is advantageously surrounded by an insulating lead so as to prevent any connection of the endoscope metal with the high frequency voltage. Preferably, the insulating sleeve of the bifurcated coaxial cable is also bifurcated, but it extends only to just in front of the neutral electrode.

In the case of the bifurcated coaxial cable, the neutral electrode is preferably an elongated metal sheet, bent slightly around the endoscope shaft and extending from one branch of the bifurcation to the other. The sheet can have projections at the four corners which are placed around the shields. Depending on the degree of placing around and also clamping, any desired fixing of the neutral electrode to the coaxial cable can be obtained.

The current density in the area of the operating zone is advantageously influenced if the neutral electrode terminates at a distance from the end of the shield.

According to a further advantageous embodiment, the neutral electrode comprises two partial electrodes extending in the direction of the loop away from the two arms of the bifurcation. Preferably, the partial electrodes do not extend quite as far from the shields as the loop. At the front and rear ends the sheets preferably have rounded portions.

As a result of the slide-like construction, the operator can reliably guide the endoscope by placing the slide-like sheet projections on the tissue to then be removed. As is known, the endoscope is operated in such a way that the cutting loop is moved forwards relative to the endoscope, made live and then slowly retracted, whereby the tissue is removed by the heating on the cutting loop.

As stated hereinbefore, the treatment electrode and neutral electrode are appropriately so shaped and positioned that the illumination, vision and washing operations are not impaired by the endoscope.

Advantageously, the leads are inductively connected to the high frequency generator, whereby advantageously, a capacitor for filtering out low frequency voltage portions is preferably provided in one lead. This, in advantageous manner avoids faradic effects in the muscular system of the patient.

A capacitor is appropriately connected in parallel to the output winding of the transmitter which with the inductor of the latter forms an oscillating circuit which is tuned in such a way that the attenuation in the oscillating circuit formed by the leads, treatment electrode and neutral electrode is minimal.

BRIEF DESCRIPTION OF THE DRAWINGS

Other and further objects of the present invention will be apparent from the following description and claims and are illustrated in the accompanying drawings which, by way of illustration show preferred embodiments of the present invention and the principles thereof and what are now considered to be the best modes contemplated for applying these principles. Other embodiments of the invention embodying the same or equivalent principles may be used and structural changes may be made if desired by those skilled in the art without departing from the invention and the scope of the appended claims.

In the drawings show:

FIG. 1 a schematic, greatly enlarged perspective view of the front end of an endoscope equipped with the electro-surgical device according to the invention.

FIG. 2 a perspective view of a further embodiment of the electro-surgical device according to the invention, without the endoscope surrounding the same.

FIG. 3 a further embodiment of the electro-surgical device according to the invention, once again without a surrounding endoscope.

FIG. 4 a schematic circuit diagram of the electro-surgical device according to the invention with a particularly suitable high frequency generator.

FIGS. 5 and 6 perspective views of two further advantageous embodiments

FIGS. 7 and 8 a perspective view and an axial section of a further advantageous embodiment.

FIG. 9 a schematic circuit diagram of an additional device for the device according to the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to FIG. 1, an endoscope 13 is axial traversed in conventional manner by a fibre optical system 17, which is spaced relative to the sides of the endoscope 13, in such a way that washing liquid can pass through there (arrow 29) and there still remains space for the axial insertion of an electro-surgical treatment device.

According to the invention, this electro-surgical treatment device comprises a coaxial cable 19 with rigid metallic shield 14 and an inner conductor 16 axially inserted together with the fibre optical system 17. Inside the metallic shaft of the endoscope 13, the shield 14 is covered in not shown manner with an insulating sleeve 22, shown in the case of the constructions of FIGS. 2 and 3.

At the front, inner conductor 16 projects somewhat from the coaxial cable 19 and passes into the treatment electrode 12, which in general comprises a loop ensur-

ing free visibility for the operator via the fibre optical systems 17.

The opposite electrode for the cutting electrode 12 is formed by a neutral electrode 11 fixed in electrically conductive manner to shield 14 and which is curved somewhat about the endoscope shaft, having a rectangular, elongated form shown in FIG. 1. Inner conductor 16 and shield 14 are connected, as shown in FIG. 4 to the two poles of a high frequency generator 15 which are not at earth potential.

At the front end of the metal shaft of the endoscope 13 is fixed a plastic extension 18, which is rounded and extends in the manner shown in FIG. 1, so as not to impair insertion, for example into the urethra. As the plastic extension 18 is an insulating body, the large-area neutral electrode 11' can also be fitted to the inside. It is then appropriately connected with the associated pole of the high frequency generator via a separate insulated conductor 14' in the endoscope, inside of via the shield 14.

As a result of the construction according to the invention, a high frequency field is only formed between shield 14 and inner conductor 16, as well as between neutral electrode 11 and treatment electrode 12, as is shown schematically in FIG. 4 by capacitors C_L and C. Due to the current conduction through the tissue fluid and tissue itself, a true resistor R is also conceivable parallel to the capacitor between neutral electrode 11 and treatment electrode 12.

The supply to connect neutral electrode 11 and the treatment electrode 12 takes place by the inductive coupling of a high frequency voltage by means of a transformer 25, whose input voltage is regulatble by a variable tap 30. Due to the inductive coupling, the output lines 14 and 16 are galvanically isolated from earth potential.

A capacitor 26 connected in lead 16 is used for filtering out the low frequency current and therefore avoids faradic effects in the muscular system of the patient. A capacitor 28 connected in parallel to the output winding 27 of transformer 25 and behind capacitor 26 forms with the output winding an oscillating circuit tuned in such a way that the attenuation in the oscillating circuit formed from C_L, C and R as well as the inductors of lines 14, 16 is minimal.

As a result of the construction according to the invention, the leakage currents only flow between lines 14, 16 and therefore do not reach the metal shaft of endoscope 13. Thus, larger current densities such as are necessary for tissue separation or coagulation only occur outside the endoscope in the operating area.

Therefore, the danger of heating outside the desired area, as well as burns to the operator is reliably avoided.

FIG. 2 shows a particularly advantageous embodiment of the electro-surgical device according to the invention in which both the inner conductor 16 and the shield 14 have a bifurcation 20. In the same way, the insulating sleeve drawn over the shield 14 is bifurcated. The production of such a bifurcation is advantageously obtained by a welded joint at point 31 indicated by a line.

As a result of the bifurcation shown in FIG. 2, a cutting loop 12 can be arranged in the shown manner between the two inner conductors 16 eminating at the end. If the treatment electrode is to be used for coagulation, a coagulation sparking ball 21 can be provided on loop 12.

The construction of FIG. 2 is particularly well suited to the arrangement of a relatively large-area neutral electrode 11 which appropriately extends between the shields 14 of the two branches of the bifurcation 20, being slightly bent about the endoscope shaft. At the end, the neutral electrode 11 has projections 23 which are securely placed around the shields 14 for securing neutral electrodes 11 and for supplying the same with voltage. The metal sheeting forming the neutral electrode simultaneously constructionally reinforces the bifurcation 20, so that the guidance of the treatment electrode 12 by the operator is aided. As is known, the axial movement of the electro-surgical device in the direction of the double arrow *f* takes place by operating a pistol-like handle on endoscope 13, not shown in the drawing.

A further advantageous embodiment is shown in FIG. 3 where the neutral electrode is broken up into two partial electrodes 11*a*, 11*b*, which in the represented manner are soldered or welded to the shields 14 in such a way that the partial electrodes extend in the same direction as cutting loop 12. Rounded portions 24 are provided at both ends. The partial electrodes 11*a*, 11*b* applied to the shields 14 in this way thus additionally form slide-like support, by means of which the electro-surgical device can be placed on the tissue to be removed. This not only ensures a reliable guidance of the device but also ensures that the tissue is removed to the predetermined depth. The electrical advantages of limiting current conduction to the operating area are completely maintained.

FIG. 5 shows a further advantageous embodiment, whereby only the front part of the electro-surgical device without the endoscope is shown. In this embodiment, two insulated cables with inner conductors 14, 16 are passed from high frequency generator 15 through the endoscope. At the front end are successively arranged the cutting loop 12 and the neutral electrode 11 constructed as a steel band. The cutting loop 12 is electrically conductively connected with the inner conductor 16, but at the other end is only fixed to the insulation surrounding the conductor 14. Conversely, the steel band 11, whose shape is similar to the cutting loop 12, is connected in electrically conductive and mechanically secure manner with the inner conductor 14, whilst the opposite end is mechanically secured to the insulation of the inner conductor 16. Since, according to the invention, the steel band 11 has the same radius as the wire loop, on retracting the loop 12 in the direction of arrow F, the band does not form an obstacle to the tissue portions removed by the loop. The neutral electrode 11 in the form of the steel band rests on the tissue in large-area form, so that good electrical contact is ensured.

FIG. 6 shows an embodiment which is substantially the same as FIG. 5, whereby however, a bifurcated coaxial cable, similar to FIGS. 2 and 3 is used. The wire loop 12 is once again fixed to the inner conductors 16, whilst the neutral conductor 11 in band form is mechanically secured to extensions 14' electrically connected with the shield 14.

In the embodiment according to FIGS. 7 and 8, the front portion of endoscope 13 itself or a coaxial connection attached thereto at the front is constructed as the neutral electrode 11. To this end, the front portion is electrically insulated relative to the rear portion or the front-fitted connection from endoscope 13 by an intermediately inserted insulating ring 36. The cutting loop 12 can at the front be passed out of the neutral electrode

11 in one of the above-described manners. In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, leading to the rear end of endoscope 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator 15 not shown in FIGS. 7 and 8.

It is also important in the case of the embodiments of FIGS. 7 and 8 that the cutting loop extends radially up to an insulating ring 35 mounted at the front on the neutral electrode 11 and can be retracted up to this. In this way, the front edge of the endoscope shaft, namely the front edge of the insulating ring 35 serves as a support for the cutting loop 12, so that the material is reliably removed therefrom. Therefore, as shown the insulating ring 35 must be rounded at the front.

Preferably, the insulating rings 35, 36 have axial attachments 37 with a reduced external diameter, by means of which a machanically secure fixing to the metal tubes is ensured.

FIG. 9 shows an additional device 32, by means of which a conventional high frequency surgical apparatus 15' with an earthed output terminal can be made usable for the purposes of the invention. The additional device 32 connected to the high frequency apparatus 15' has at the inlet a transformer 33 with parallel-connected capacitor 34 for tuning to the resonant frequency of the output circuit of the high frequency apparatus 15'. The output winding of transformer 33 is preferably regulatable by means of a loop arm 38 in such a way that the inductive output transformer 25 can receive voltages of varying sizes.

Via a capacitor 26, the output winding of transformer 25 is applied to the two output terminals of the additional device 32, where the leads 14, 16 can be applied.

In this way the high frequency apparatus 15' acquires an output with fluctuating potential, as is necessary for the connection of the electro-surgical device according to the invention.

The invention is not limited to the embodiments described and represented hereinbefore and various modifications can be made thereto without passing beyond the scope of the invention.

What is claimed is:

1. In combination: an endoscope having an endoscope body of substantially tubular shape, and an electro-surgical device comprising a treatment electrode projecting at one end from said endoscope body and a neutral electrode arranged adjacent said treatment electrode, insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator, and means for connecting said neutral electrode to the other pole of a high-frequency generator, said endoscope body having an-insulating projection extending over a portion of the periphery of said endoscope body at said one end and having a front edge, said neutral electrode being located within said endoscope body and spaced a distinct distance inwardly from said front edge, a space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with liquid to provide electrical conductance between said electrodes.

2. The combination of claim 1, wherein said insulated cable means and said means for connecting said neutral electrode to said other pole comprise coaxial cable means with shielding means forming one of said connecting means and being insulated relative to said endoscope body.

3. The combination according to claim 2, wherein said shielding means is constructed as a rigid sleeve in which said treatment electrode is adapted to be moved back and forth relative to said endoscope body through said coaxial cable means.

4. The combination according to claim 2, wherein said neutral electrode is fixed directly to said shielding means of said coaxial cable means.

5. The combination according to claim 4, wherein the neutral electrode is constructed as an elongated metal sheet slightly bent within said endoscope body and extending over said coaxial cable means.

6. The combination according to claim 2, comprising an insulating sleeve surrounding said coaxial cable means.

7. The combination according to claim 6, wherein said insulating sleeve is bifurcated and extends approximately to said neutral electrode.

8. The combination according to claim 7, wherein said neutral electrode is an elongated metal sheet slightly bent within said endoscope body and extending from one branch of said bifurcated insulating sleeve to the other.

9. The combination according to claim 8, wherein said sheet has projections at its four corners, two each of which are placed around the respective branches of said bifurcated sleeve.

10. The combination according to claim 2, wherein said neutral electrode terminates at a distance from said shielding means.

11. The combination according to claim 1, wherein said neutral electrode is secured to and insulated from said endoscope body on the inside of said insulating projection.

12. The combination according to claim 1, wherein said means for connecting said neutral electrode to said high-frequency generator is an insulated conductor secured in said endoscope body.

13. The combination according to claim 2, wherein said coaxial cable means has a bifurcation at that end of the endoscope body adjacent said projection, two inner conductors eminating from said bifurcation, and a loop interconnecting said two inner conductors and forming said treatment electrode.

14. The combination according to claim 1, wherein a coagulation sparking ball is fitted to said treatment electrode.

15. The combination according to claim 1, comprising a high-frequency generator, and wherein said cable means and said connecting means are inductively coupled to said high-frequency generator.

16. The combination according to claim 15, wherein a capacitor is connected in one of said cable means and said connecting means for filtering out low-frequency voltage.

17. The combination according to claim 15, wherein said generator comprises a transformer with an output winding having an inductor, a capacitor being connected parallel to said output winding and forming an oscillating circuit with said inductor, said circuit being tuned such that the attenuation in said circuit formed by said cable means, said connecting means, treatment electrode and neutral electrode is minimal.

18. The combination according to claim 15, comprising means for potential isolation connected between said high-frequency generator and said cable means and said connecting means respectively.

19. The combination according to claim 18, wherein said potential isolation means comprises a transformer, a capacitor connected parallel to said transformer, said high-frequency generator having an output circuit, said transformer and said output circuit being tuned in resonance.

20. The combination according to claim 19, comprising an inductive transformer connected to said transformer, said cable means and said connecting means being connected to said inductive transformer.

* * * * *

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ArthroCare Reports Revenue Growth of 31 Percent for the First Quarter; Recurring EPS of $0.11 Reduced by $1.2 Million Non-Recurring Acquisition Adjustment

SUNNYVALE, Calif.--(BUSINESS WIRE)--April 28, 2004--ArthroCare(R) Corp. (Nasdaq:ARTC), a multi-business medical device company that develops minimally invasive surgical products, announced today that in the first quarter ended March 31, 2004, the company reported product revenues of $34.3 million, a 30 percent increase over the $26.4 million recorded in the same quarter of the previous year. Total revenues, which include product revenues and royalties, for the first quarter were $35.6 million, a 31 percent increase over the $27.2 million reported in the first quarter of 2003.

ArthroCare reported first quarter net income of $1.6 million, or $0.07 per diluted share, after the effect of a $1.2 million non-recurring inventory charge to income related to the acquisition of Parallax Medical in January 2004.

Excluding this charge, tax effected at 27 percent, ArthroCare generated net income of $2.4 million, or $0.11 per diluted share, for the first quarter of 2004, compared to net income of $594,000, or $0.03 per diluted share, reported in the same quarter of 2003.

Q1 SUMMARY TABLE

	Q104 GAAP (reported)	Q104 Non-GAAP (recurring) (a)	Q403	Q103
Product Sales	$34.3 M	$34.3 M	$31.3 M	$26.4 M
License Fees, Royalties and Other Revenues	$1.3 M	$1.3 M	$1.2 M	$752,000
Total Revenues	$35.6 M	$35.6 M	$32.5 M	$27.2 M
Net Income	$1.6 M	$2.4 M	$2.8 M	$594,000
Earnings Per Diluted Share	$0.07	$0.11	$0.13	$0.03

(a) ArthroCare is presenting recurring, non-GAAP financials because the non-recurring inventory charge is material information.

REVENUE

In addition to first quarter product sales of $34.3 million, license fees, royalties and other revenue were $1.3 million in the first quarter of 2004 compared to $752,000 in the first quarter of 2003. International sales remained strong, increasing approximately 45 percent compared to the same period last year and representing 27 percent of product sales during the quarter.

BUSINESS UNIT PERFORMANCE

During the first quarter, ArthroCare generated strong year-over-year revenue growth across all of its business units.

Sports Medicine sales increased 14 percent during the quarter ended March 31, 2004 compared with the same period of 2003 and represented 68 percent of total product revenue. Sales in the Spine business unit (which include a partial quarter of direct sales of Parallax products) increased 107 percent during the quarter compared to the first quarter of 2003 and represented 16 percent of product sales.

The first quarter increase in ENT product sales over the comparable period of last year was 88

percent, with ENT sales representing 16 percent of product revenue during the quarter. Tonsillectomy sales continue to lead this growth, particularly in the United States where ArthroCare estimates Coblation was used in approximately 12 percent of cases during the first quarter -- compared to 11 percent in the prior quarter.

OPERATIONS

Gross margin on product sales was 62 percent in the first quarter including the charge related to the inventory acquired in connection with the Parallax acquisition. Excluding this charge, gross margin was 65 percent compared to 67 percent in the year-ago quarter and 63 percent in the fourth quarter of 2003. ArthroCare expects its gross margin on product sales to return to approximately 68 percent by the third quarter.

Operating expenses for the first quarter increased approximately 15 percent compared to the first quarter a year ago and the immediately preceding quarter. Sales and marketing activities related to the relatively large number of new products recently introduced, including the Parallax product suite, drove the quarter-to-quarter increase.

Due principally to lower legal expenses, general and administrative expenses decreased as a percentage of product revenue from 15 percent in the year-ago quarter to 10 percent in the quarter ended March 31, 2004. Sales and marketing and research and development expenses were essentially flat as a percentage of product revenue compared to the first quarter of 2003.

"ArthroCare delivered a solid financial performance during the first quarter with strong organic revenue growth throughout the company," said Michael A. Baker, president and chief executive officer for ArthroCare. "We completed a number of key accomplishments during the quarter, including closing the Parallax acquisition and integrating the company into our organization, as well as winning a permanent injunction against Smith & Nephew. These activities, along with the successful execution of our other important business strategies, have positioned us well to meet our 2004 financial objectives."

RECENT CORPORATE DEVELOPMENTS

-- A federal judge granted ArthroCare's motion for a permanent injunction against Smith & Nephew as part of ArthroCare's patent infringement lawsuit against the company. In its order, a U.S. District Court in Delaware granted ArthroCare's motion for permanently enjoining Smith & Nephew from manufacturing, using or selling in the United States surgical devices (the Saphyre, Control RF and ElectroBlade) that were found to infringe ArthroCare's patents. Smith & Nephew has indicated it plans to appeal this ruling.

-- ArthroCare completed the acquisition of Medical Device Alliance, Inc. and its wholly owned subsidiary Parallax Medical, Inc., a leader in products for bone access, percutaneous injection of bone cement and bone augmentation in the spine. Physicians use Parallax products during a variety of orthopedic procedures, including treatments for vertebral compression fractures caused by osteoporosis or spinal tumors. ArthroCare acquired Parallax for $28 million in cash and future revenue milestone payments. The company expects the acquisition to contribute approximately $7-8 million in product sales during the year, break even in fiscal 2004 and be accretive thereafter.

-- The company announced a new business strategy designed to expand its presence in the spine surgeon market. ArthroCare is establishing a network of leading independent spine surgery distributors to market and sell its spine surgery product suite worldwide.

-- ArthroCare named Dr. Barbara D. Boyan to its board of directors. Dr. Boyan currently holds a number of prominent positions in the fields of orthopedics and tissue engineering, including the Prince Gilbert, Jr. Chair in Tissue Engineering at the Georgia Institute of Technology (Georgia Tech) in Atlanta. Appointed by the U.S. Congress, she also serves as

the chair of the orthopedic device panel for the Center of Devices and Radiological Health of the U.S. Food and Drug Administration (FDA). Additionally, she has served on three National Institutes of Health (NIH) scientific review panels.

-- ArthroCare introduced the next-generation Micro Discoblator(R) device. The new device is designed to improve the outcome of patients undergoing microdiscectomy by enabling surgeons to more precisely control the amount of tissue being removed from spinal discs and preserve the annulus. This approach is intended to cause less damage to the disc than traditional disc decompression procedures and to make the procedure faster and easier for surgeons.

-- The company expanded its Sports Medicine product lines for knee and shoulder surgeries. ArthroCare will market and distribute Biocomposites' BiLok(R) ST screw for anterior cruciate ligament (ACL) reconstruction, which is designed for physicians who prefer to use hamstring tendons in a looped bundle for ACL reconstruction. ArthroCare also introduced its ParaLOK anchor for shoulder surgery, which will be available in the second quarter of 2004. It is designed for patients who undergo shoulder surgery for torn rotator cuffs or procedures to treat shoulder instability, including Bankart repairs.

-- ArthroCare introduced two new SpineWands(TM) for use during DISC Nucleoplasty(R) for the treatment of contained herniated discs in obese and overweight patients and for tissue ablation in larger discs of the spine. The Perc-D(R) XL SpineWand(TM) is ideal for use during DISC Nucleoplasty procedures on overweight and obese patients because it provides surgeons with a longer needle to access their discs. ArthroCare developed the Perc-D(R)X SpineWand(TM) to meet physician demand for a wand that can be used to treat patients with larger contained herniations who were previously not candidates for percutaneous disc decompression.

BUSINESS OUTLOOK

The following statements are based on current expectations on April 28, 2004. These statements are forward-looking, and actual results may differ materially. These statements do not include the potential impact of any new businesses or license agreements the company may enter in future periods.

ArthroCare's business outlook for fiscal 2004 remains unchanged – except for a decrease in the expected tax rate – and is as follows:

-- ArthroCare expects earnings per share (EPS) for fiscal 2004 to be between $0.52 and $0.56, with an assumed share count of 23.1 million.

-- ArthroCare anticipates fiscal 2004 product revenue to grow in excess of 20 percent compared to 2003 revenues.

-- The company expects to improve operating margins by 4-5 percentage points in 2004 compared with 2003.

-- The company also currently expects the effective tax rate for 2004 to be approximately 27 percent.

CONFERENCE CALL

ArthroCare will hold a conference call with the financial community to discuss these results at 7:30 a.m. ET/4:30 a.m. PT today. The call will be simultaneously Web cast by CCBN and can be accessed on ArthroCare's Web site at www.arthrocare.com. The Webcast will remain available through May 12, 2004. A telephonic replay of the conference call can be accessed by dialing 800-633-8284 and entering pass code number 21192300.

ABOUT ARTHROCARE

Corporate Information

ArthroCare Corp. (www.arthrocare.com), headquartered in Sunnyvale, Calif., is a multi-business medical device company that develops, manufactures and markets minimally invasive surgical products, many of which are based on its patented Coblation technology. Coblation uses low-temperature radio-frequency energy to gently and precisely dissolve rather than burn soft tissue, minimizing damage to healthy tissue. ArthroCare targets a multi-billion dollar market opportunity across several medical specialties, significantly improving surgical procedures and enabling new, minimally invasive procedures. ArthroCare's Coblation-based devices have been used in more than two million surgical procedures worldwide. The company has developed and marketed Coblation-based products for arthroscopic, spine/neurologic, ear, nose and throat, cosmetic, urologic, gynecologic and laparoscopic/general surgical procedures, and continues research in other areas.

SAFE HARBOR STATEMENTS

Except for historical information, this press release includes forward-looking statements. These statements include, but are not limited to, the company's stated business outlook for fiscal 2004, continued strength of the company's fundamental position, the strength of the company's technology, the company's belief that strategic moves will enhance achievement of the company's long term potential, the potential and expected rate of growth of new businesses, continued success of product diversification efforts, and other statements that involve risks and uncertainties. These risks and uncertainties include, but are not limited to the uncertainty of success of the company's non-arthroscopic products, competitive risk, uncertainty of the success of strategic business alliances, uncertainty over reimbursement, need for governmental clearances or approvals before selling products, and the uncertainty of protecting the company's patent position. These and other risks and uncertainties are detailed from time to time in the company's Securities and Exchange Commission filings, including ArthroCare's Form 10-K for the year ended December 31, 2003. Forward-looking statements are indicated by words or phrases such as "anticipates," "estimates," "projects," "believes," "intends," "expects," and similar words and phrases. Actual results may differ materially from management expectations.

ARTHROCARE CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three Months Ended			Three Months Ended		
	March 31 2004	December 31 2003	Variance	March 31 2004	March 31 2003	Variance
Revenues:						
Net Product Sales	$34,292	$31,310	$ 2,982	$34,292	$26,449	$ 7,843
Royalties, fees and other	1,297	1,201	96	1,297	752	545
Total revenues	35,589	32,511	3,078	35,589	27,201	8,388
Cost of product sales	13,080	11,616	(1,464)	13,080	8,598	(4,482)
Gross profit	22,509	20,895	1,614	22,509	18,603	3,906
Operating expenses:						
Research and development	3,120	2,322	(798)	3,120	2,646	(474)
Sales and marketing	14,328	12,668	(1,660)	14,328	11,519	(2,809)
General and administrative	3,318	2,863	(455)	3,318	3,912	594
Total operating expenses	20,766	17,853	(2,913)	20,766	18,077	(2,689)

Income from operations	1,743	3,042	(1,299)	1,743	526	1,217
Interest and other income, net	406	721	(315)	406	348	58
Income before income tax provision	2,149	3,763	(1,614)	2,149	874	1,275
Income tax provision	580	957	377	580	280	(300)
Net income	$ 1,569	$ 2,806	(1,237)	$ 1,569	$ 594	975
Basic net income per share	$0.07	$0.13	-$0.06	$0.07	$0.03	$0.04
Shares used in computing basic net income per share	20,996	20,799		20,996	21,168	
Diluted net income per common share	$0.07	$0.13	-$0.06	$0.07	$0.03	$0.04
Shares used in computing diluted net income per share	22,785	22,415		22,785	21,736	

ARTHROCARE CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three Months Ended				
	March 31 2004	Adjustments	March 31 2004	December 31 2003	Variance
	Reported		Recurring		
Revenues:					
Net Product Sales	$34,292	$ -	$34,292	$31,310	$ 2,982
Royalties, fees and other	1,297		1,297	1,201	96
Total revenues	35,589	-	35,589	32,511	3,078
Cost of product sales	13,080	(1,204)	11,876	11,616	(260)
Gross profit	22,509	1,204	23,713	20,895	2,818
Operating expenses:					
Research and development	3,120		3,120	2,322	(798)
Sales and marketing	14,328		14,328	12,668	(1,660)
General and					

administrative	3,318		3,318	2,863	(455)
Total operating expenses	20,766	-	20,766	17,853	(2,913)
Income from operations	1,743	1,204	2,947	3,042	(95)
Interest and other income, net	406		406	721	(315)
Income before income tax provision	2,149	1,204	3,353	3,763	(410)
Income tax provision	580	325	905	957	52
Net income	$ 1,569	$ 879	$ 2,448	$ 2,806	$ (358)
Basic net income per share	$0.07	$0.04	$0.12	$0.13	-$0.01
Shares used in computing basic net income per share	20,996	20,996	20,996	20,799	
Diluted net income per common share	$0.07	$0.04	$0.11	$0.13	-$0.02
Shares used in computing diluted net income per share	22,785	22,785	22,785	22,415	

	Three Months Ended				
	March 31 2004	Adjustments	March 31 2004	March 31 2003	Variance
	Reported		Recurring		
Revenues:					
Net Product Sales	$34,292	$ -	$34,292	$26,449	$ 7,843
Royalties, fees and other	1,297		1,297	752	545
Total revenues	35,589	-	35,589	27,201	8,388
Cost of product sales	13,080	(1,204)	11,876	8,598	(3,278)
Gross profit	22,509	1,204	23,713	18,603	5,110
Operating expenses:					
Research and development	3,120		3,120	2,646	(474)
Sales and marketing	14,328		14,328	11,519	(2,809)
General and administrative	3,318		3,318	3,912	594
Total operating expenses	20,766	-	20,766	18,077	(2,689)
Income from operations	1,743	1,204	2,947	526	2,421
Interest and other					

FORM 10-K

ARTHROCARE CORP - ARTC

Filed: March 15, 2004 (period: December 31, 2003)

Annual report which provides a comprehensive overview of the company for the past year

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2003

Commission File Number: 0-27422

ARTHROCARE CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	**94-3180312**
(State or other jurisdiction of Incorporation or organization)	**(I.R.S. employer Identification number)**

680 Vaqueros Avenue, Sunnyvale, California 94085
(Address of principal executive offices and zip code)

(408) 736-0224
(Registrant's telephone number, including area code)

Securities registered pursuant to 12 (b) of the Act:	**None**
Securities registered pursuant to section 12 (g) of the Act:	**Common Stock, $0.001 Par Value; Preferred Share Purchase Rights**

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No ☐

As of June 30, 2003, the aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately $181,555,000 (based upon the closing sales price of such stock as reported by The NASDAQ Stock Market on such date). Shares of Common Stock held by each officer, director, and holder of 5% or more of the outstanding Common Stock on that date have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 27, 2004, the number of outstanding shares of the Registrant's Common Stock was 21,141,885.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by items 10, 11, 12, and 13 of Part III of Form 10-K is incorporated by reference from the Registrant's proxy statement for the 2004 Annual Stockholders' Meeting, which will be filed, with the Securities and Exchange Commission within 120 days after the close of the Registrant's fiscal year ended December 31, 2003.

arthroscopy product sales are being generated by the sale of disposables for use in knee procedures. We expect our sales to continue to be strong in 2004, as we continue to increase our presence in Europe and add the MDA product line to our sales mix.

Royalties, fees, and other revenues consist mainly of revenue from the licensing of our products and technology. Royalties, fees, and other revenues increased to $4.1 million in 2003 from $3.8 million in 2002. Royalties, fees, and other revenues decreased in 2002 from $8.1 million for fiscal 2001, primarily due to the cancellation of agreements in 2001 with distribution partners resulting in recognition of $5.5 million in fees that previously had been deferred.

Cost of Product Sales

Cost of product sales consists of manufacturing costs, material costs, labor costs, manufacturing overhead, warranty and other direct product costs. Additionally, cost of product sales includes amortization of controller unit placements under a program whereby we maintain ownership of controller units shipped to customers, with the costs being capitalized and amortized into cost of product sales over the useful life of the controller unit. Cost of product sales for 2003 was $37.9 million, or 33% of product sales, compared to $33.4 million, or 39% of product sales for 2002 and $27.7 million, or 39% of product sales, for fiscal 2001.

Gross product margin as a percentage of product sales increased to 67% in 2003 from 61% in both 2002 and 2001. The increase in gross margin percentage compared to 2002 was mainly attributable to the increased efficiency of our manufacturing operations resulting mostly from the transition of manufacturing operations to our Costa Rica facility and increased production volume to cover our increased product sales, partially offset by the increased controller unit amortization and the lower gross margin on sales of Atlantech products. The decrease in gross product margin in 2002 compared to 2001 was mainly attributable to increased average selling prices of disposable devices, increased manufacturing efficiency due to a half year of manufacturing at our Costa Rica facility and increased production volume, offset by increased controller unit amortization and the first of our Atlantech sales. The 2002 gross product margin was additionally impacted by a $2.5 million charge to revalue inventory to bring it into line with our new, lower manufacturing cost structure and a $0.3 million charge relating to purchase price adjustments to inventory due to our acquisition of Atlantech.

We expect gross product margins to continue at around 2003 levels as we continue to experience savings from our Costa Rica manufacturing facility.

Operating Expenses

Research and development expense increased to $10.6 million, or 9% of total revenues, in 2003 from $8.8 million, or 10% of total revenues, in 2002 and from $8.0 million, or 10% of total revenues, in 2001. The increase in research and development expenses in 2003 as compared to 2002 is primarily due to our continued investment in Coblation technology, which we believe is essential for us to maintain and improve our competitive position. The increase consists of $1.2 million in increased compensation and related expenses due to increasing headcount, and $0.6 million in increased prototype development costs. The increase in research and development expenses in 2002 as compared to 2001 was primarily due to increased compensation and related expenses of $0.1 million due to increasing headcount, and increased development prototype materials expense of $0.1 million, and $0.5 million in increased facility and information system costs in conjunction with expanding our infrastructure. We believe that investment in our Coblation technology is essential for us to maintain our competitive position. We expect to increase the dollar amount of research and development expenses through continued expenditures on new product development, including for the newly acquired MDA products, regulatory affairs, clinical studies and patents, with expenses as a percentage of product sales to remain essentially flat.

Sales and marketing expense increased to $47.3 million, or 40% of total revenues, in 2003 from $36.5 million, or 41% of total revenues, in 2002, and from $29.7 million, or 38% of total revenues, in 2001. Increased